

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Continuation Application of: Reiley et al.

Examiner: J. Woo

Serial No. : 08/911,805

Group Art Unit: 3731

Filed : August 15, 1997

For : A Sterile Kit for Holding a Single Use, Expandable Structure Intended for Deployment in Bone

PRELIMINARY AMENDMENT A

Commissioner of Patents
and Trademarks
Washington, D.C. 20231

Sir:

Please amend this application before calculation of the filing fee as follows:

IN THE SPECIFICATION:

Amend the paragraph beginning on Page 1, Line 5 and ending at Page 1, Line 16 as follows (the paragraph also is presented in clean form, attached).

This application is a continuation of co-pending application Serial No. 08/911,805 filed August 15, 1997, which is a continuation-in-part of U.S. Patent Application Serial No. 08/871,114, filed June 9, 1997, which is a continuation-in-part of U.S. Patent Application Serial No. 08/659,678, filed June 5, 1996, which is a continuation-in-part of U.S. Patent Application Serial No. 08/485,394, filed June 7, 1995, which is a continuation-in-part of U.S. Patent Application Serial No. 08/188,224, filed January 26, 1994 entitled, "Improved Inflatable Device For Use In Surgical Protocol Relating To Fixation Of Bone."

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IN THE CLAIMS:

Please cancel claims 1 through 6.

New claims 7 through 17 are presented for prosecution, as attached in clean form
(according to 37 C.F.R. §1.121(c)(3)):

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Clean Version of Amended Paragraph

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Clean Version of Pending Claims 7-17

7 (New). A method for treating bone comprising the steps of:

inserting inside bone a device comprising a body adapted to undergo expansion in cancellous bone to compact cancellous bone, the body including material that plastically deforms as a result of the expansion in cancellous bone, and

expanding the body in the cancellous bone to plastically deform the body while compacting cancellous bone, whereby the body cannot be relied upon to reach a desired geometry during subsequent expansion in bone,

removing the plastically deformed body from the bone, and

instructing against reuse of the plastically deformed body.

8 (New). A method according to claim 7

further including the step of displacing at least a portion of a cortical bone section of the bone while the body expands in cancellous bone.

9 (New). A method for treating bone comprising the steps of:

inserting inside cortical bone a device comprising a body adapted to undergo expansion in cortical bone to displace at least a portion of the cortical bone, the body including material that plastically deforms as a result of the expansion in cortical bone,

expanding the body in the cancellous bone to plastically deform the body while displacing at least a portion of the cortical bone, whereby the body cannot be relied upon to reach a desired geometry during subsequent expansion in bone,

removing the plastically deformed body from the bone, and

instructing against reuse of the plastically deformed body.

10 (New). A method according to claim 7 or 9

wherein the material comprises vinyl.

11 (New). A method according to claim 7 or 9

wherein the material comprises nylon.

12 (New). A method according to claim 7 or 9

wherein the material comprises polyethylene.

13 (New). A method according to claim 7 or 9

wherein the material comprises an ionomer.

14 (New). A method according to claim 7 or 9
wherein the material comprises polyurethane.

15 (New). A method according to claim 7 or 9
wherein the material comprises polyethylene tetrathalate.

16 (New). A material according to claim 7 or 9
wherein the material comprises latex.

17 (New). A method according to claim 7 or 9
wherein the material comprises silicone.

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REMARKS

Claims 1 through 6 have been canceled. New claims 7 to 17 have been added to define features of applicant's invention with better clarity. Among these, new claims 7 and 9 are the independent method claims.

As defined in the claims, a method inserts inside bone a device comprising a body adapted to undergo expansion in cancellous bone. The body includes material that plastically deforms as a result of expansion in cancellous bone. The method expands the body in the cancellous bone, which plastically deforms the body, to achieve a desired therapeutic effect. As defined in claim 7, the expansion compacts cancellous bone. As defined in claim 9, the expansion displaces at least a portion of the cortical bone. As a result of the plastic deformation, the body cannot be relied upon to reach a desired geometry during subsequent expansion in bone. Accordingly, the method removes the plastically deformed body from the bone, and instructs against reuse of the plastically deformed body.

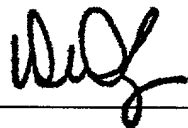
Support for the subject matter of the claims is found, e.g., on page 23, line 12 to page 24, line 20, and page 25, line 25 to page 26, line 4. By definition, "plastic deformation" means "capable of being deformed continuously and permanently in any direction without rupture" (Webster Collegiate Dictionary), which is a characteristic of the body described in the Specification, when expanded in the presence of cancellous bone, see, e.g., page 23, lines 12 to 28.

The prior art, including Scholten et al (US 5,108,404), does not teach or suggest that contact of an expandable body with cancellous bone can "create material stress during first use" to "significantly alter the molded morphology of the structure" (i.e., plastically deform the body), "making future performance of the structure unpredictable." (Specification page 23, lines 16 to 20). This characteristic of cancellous bone and the attendant result was not appreciated or recognized prior to the invention. The prior art therefore does not teach, or suggest, or comprehend that the treatment of bone that expands a body in cancellous bone for a desired therapeutic purpose should include the step of instructing against subsequent reuse of the plastically deformed body.

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Allowance of claims 7 to 17 is therefore believed to be warranted and is respectfully
requested.

Respectfully submitted,

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